

NOV 20 2003

510(K) SUMMARY

Submitter's Name: David E. Curtin, RAC

Address: 1620 Waukegan Rd. MPGR-A2E

Phone: (847) 473-6079

Fax: (847) 473-6952

Contact: David E. Curtin

Date Prepared: May 30, 2003

Trade Name: HomeChoice APD Set with Lineo Connector

Common Name: Sets, Administration, for Peritoneal Dialysis, Disposable

Classification Name: Peritoneal Dialysis System and Accessories 21 CFR 876.5630

Equivalent Predicate: HomeChoice APD Set (Baxter Healthcare Corp., K923065), HomeChoice Low Recirculation Volume APD Set (Baxter Healthcare Corp., K012988), High Dose Disconnect Cap and MiniCap with Povidone Iodine (Baxter Healthcare Corp., K972579) and Disconnect Caps with Povidone Iodine (Baxter Healthcare Corp., K895631)

Device Description: HomeChoice APD Set with Lineo Connector is a disposable tubing administration set used in automated peritoneal dialysis therapies. It provides for connection of the patient and the peritoneal dialysis solutions to the automated cyclor.

Intended Use: The HomeChoice APD Set with Lineo Connector is intended for use with the HomeChoice Automated Personal Cyclor.

**Summary of the
Technological
Characteristics
Compared to the**

The general design and material of the HomeChoice APD Set with Lineo Connector is to the HomeChoice APD Set (K923065 and K012988) and High Dose Disconnect Cap/MiniCap (K972579 and K895631) in that it incorporates the disinfectant feature of the Disconnect Cap/MiniCap into the patient connector of the set. The technological characteristics of the HomeChoice APD Set with Lineo Connector do not raise any new types of safety and effectiveness issues, when compared to the predicate product.

Predicate Device:

HomeChoice APD Set (Baxter Healthcare Corp), HomeChoice Low Recirculation Volume APD Set (Baxter Healthcare Corp.), High Dose Disconnect Cap and MiniCap with Povidone Iodine (Baxter Healthcare Corp.) and Disconnect Caps with Povidone Iodine (Baxter Healthcare Corp)

Clinical Data:

N/A

Conclusions Drawn

Components of the subject HomeChoice APD Set with Lineo Connector have met the biological requirements of ISO 10993-1: Biological Evaluation of Medical devices – Part: Guidance on selection of tests.

Sterilization of the HomeChoice APD Set with Lineo Connector is by a method determined and validated to ensure an SAL of $\geq 10^{-6}$. Functional and physical testing is performed prior to product release

**Additional
Information**

Requested by FDA:

None to date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 20 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

David E. Curtin, RAC
Associate Director, Regulatory
Affairs Renal Division
Baxter Healthcare Corporation
1620 Waukegan Road
MCGAW PARK IL 60085

Re: K031676

Trade/Device Name: HomeChoice Automated PD Set with Lineo Connector; #5C4469Q, 5C4468Q
HomeChoice Integrated APD Set with Lineo Connector; #5C4531Q
HomeChoice Low Recirculation Volume APD Set with Lineo Connector; #5C8302Q
and Lineo Opticap; #5C4599Q

Regulation Number: 21 CFR§ 876.5630

Regulation Name: Peritoneal Dialysis System and Accessories

Regulatory Class: II

Product Code: 78 KDJ

Dated: August 29, 2003

Received: September 2, 2003

Dear Mr. Curtin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

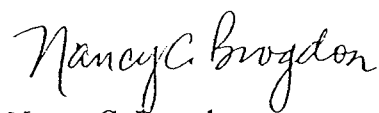
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K031676

Device Name: HomeChoice Integrated APD Set with Lineo Connector

Indications For Use:

The HomeChoice Integrated APD Set with Lineo Connector is intended for delivery of peritoneal dialysis therapy and is compatible with the HomeChoice Automated PD System only, and is to be used with the MiniCap Extended Life PD Transfer Set, Easy-Lock Extended Life PD Transfer Set, or Easy-Lock Transfer Set.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

Indications for Use Statement

510(k) Number (if known): K031676

Device Name: HomeChoice Low Recirculation Volume APD Set with Lineo Connector

Indications For Use:

The HomeChoice Low Recirculation Volume APD Set with Lineo Connector is intended for delivery of peritoneal dialysis therapy in pediatric and adult renal failure patients requiring fill volumes of 60 – 1000 ml, using only the HomeChoice Automated Personal Cyclor with Low Fill Mode Drain Logic.

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Indications for Use Statement

510(k) Number (if known): K031676

Device Name: Lineo OptiCap

Indications For Use:

The Lineo OptiCap is for protection of the Lineo Connector (patient line) of APD Disposable Sets with Lineo Connector that are intended for delivery of peritoneal dialysis therapy.

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Division of Reproductive, Abdominal,
and Radiological Devices

Indications for Use Statement

510(k) Number (if known): K031676

Device Name: HomeChoice Automated PD Set with Lineo Connector

Indications For Use:

The HomeChoice Automated PD Set with Lineo Connector is intended for delivery of peritoneal dialysis therapy and is compatible with the HomeChoice Automated PD System only, and is to be used with the MiniCap Extended Life PD Transfer Set, Easy-Lock Extended Life PD Transfer Set, or Easy-Lock Transfer Set.

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